This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

Bergeson & Campbell, P.C.

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April 6, 1999

Via Hand Delivery

Mr. Dennis Utterback
Special Review and Reregistration Division
Office of Pesticide Programs
United States Environmental Protection Agency
Mail Code 7508W
401 M Street, S.W.
Washington, D.C. 20460

Re: <u>DDVP Preliminary Risk Assessment</u>

Dear Dennis:

As promised earlier today when I spoke with Jack Housenger, appended is a document entitled Critical Studies on Dichlorvos Which Must be Evaluated for the EPA HED RED. Also appended is a copy of each of the studies noted in this document. Amvac Chemical Corporation emphasizes that this list reflects only those studies of which Amvac is aware and believes to be of critical importance for purposes of EPA's Preliminary Risk Assessment of DDVP. Amvac is in the process of reviewing additional studies to assess whether they materially affect the Preliminary Risk Assessment for DDVP, and will forward all such additional studies under separate cover.

Additionally, and as discussed with Mr. Housenger this morning, Amvac has tentatively agreed to meet with EPA representatives on Thursday, April 15, 1999, at 2:00 p.m. (EDT) to discuss the Risk Assessment. We will forward additional details regarding the meeting and representatives who will participate in the meeting on Amvac's behalf.

Bergeson&Campbell, P.C.

Mr. Dennis Utterback April 6, 1999 Page 2

As always, please call if you have any questions.

Sincerely,

Lynn L. Bergeson

Attachments

cc: Mr. Jack E. Housenger (w/o attachments) (via facsimile)

Mr. Ian S. Chart (w/o attachments) (via facsimile)

Marcia E. Mulkey, Esquire (w/o attachments) (via facsimile)

Critical Studies on Dichlorvos which Must be Evaluated for the EPA HED RED

Human and Animal Health Studies

Studies that are critical to an estimate of the inhaled dose to rats in the chronic inhalation rat study by Blair et al.

- Stevenson, D.E., and D. Blair. (1977). The uptake of dichlorvos during long-term inhalation studies. *Proc. Eur. Soc. Toxicol.* 18: 215-217.
- Cochran, R.C., T.A. Formoli, K.F. Pfeifer, and C.N. Aldous. (1997). Characterization of risks associated with the use of molinate. *Reg. Tox. & Pharm.* 25:146-157.

Studies that determine the effects of single/repeated exposures of dichloryos via inhalation.

- Anonymous (1967). Safe use of pesticides in public health. WHO Tech. Report Series No. 356, WHO, Geneva, p. 46054
- Durham, W.F., T.B. Gaines, R.H. McCauley, Jr., V.A. Sedlak, A.M. Mattson, and W.J. Hayes, Jr. (1957). Studies on the toxicity of 0,0-dimethyl-2,2-dichlorovinyl phosphate (DDVP). Am. Med. Assoc. Arch. Ind. Health 15: 340-349.
- Foll, C.V., C.P. Pant, and P.E. Lietaert. (1965). A large-scale field trial with dichlorvos as a residual fumigant insecticide in northern Nigeria. *Bull. World Health Organ*. 32:531-550.
- Funckes, A.J., S. Miller, and W. Hayes (1963). Initial field studies in Upper Volta with dichlorvos residual fumigant as a malaria eradication technique. *Bull. Org. mond. Sante Bull. Wld. Hlth Org.* 29:243-246.
- Gratz, N. G., P. Bracha, and A. Carmichael. (1963). A village scale trial with dichlorvos as a residual fumigant insecticide in southern Nigeria. *Bull. Org. mond. Sante Bull. Wld. Hlth Org.* 29:251-270.
- Hayes, W. J. (1961). Safety of DDVP for the disinsection of aircraft. Bull. Org. mond. Sante Bull. Wld. Hlth Org. 24:629-633.
- Hunter, C.G. (1969). Dichlorvos: Human Inhalation Studies. Shell Research Limited, Sittingbourne, Kent, England.

Page 1 4/06/99

- Hunter, C.G. (1970). Dichlorvos: Inhalational exposure with human subjects. Part 1 (TLGR.0061.70) and Part 2 (TLGR.0067.70). Shell Research Limited, Sittingbourne, Kent, England.
- The Kettering Laboratory. (1965). Evaluation of Safety in the Use of Vapona Insecticide Resin Vaporizers. University of Cincinnati, June, 1965.
- Leary, J.S., W.T. Keane, C. Fontenot, E.F. Feichmeir, D. Schultz, B.A. Koos, L. Hirsch, E.M. Lavor, C.C. Roan, and C.H. Hine. (1974). Safety evaluation in the home of polyvinyl chloride resin strip containing dichlorvos (DDVP). *Arch Environ. Health* 29:308-314.
- Mathis, W., A. St. Cloud, M. Eyraud, S. Miller, and J. Hamon. (1963). Initial field studies in Upper Volta with dichlorvos residual fumigant as a malaria eradication technique. 2. Entomological evaluation. *Bull. Org. mond. Sante (Bull. Wld Hlth Org.)* 29:237-241.
- Quaterman, K.D., M. Lotte, and H.F. Schoof. (1963). Initial field studies in Upper Volta with dichlorvos residual fumigant as a malaria eradication technique. 1. General considerations. *Bull Wld Hlth Org.* 29:231-235.
- Rasmussen, W.A., J.A. Jensen, W.J. Stein, and W.J. Hayes. (1963). Toxicological studies of DDVP for disinsection of aircraft. Aerospace Medicine (July):593-600
- Stein, W.J., S. Miller, and L.E. Fetzer, Jr. (1966). Studies with dichlorvos residual fumigant as a malaria eradication technique in Haiti. III. Toxicological studies. *Am. J. trop. Med. Hyg.* 15(5):672-675.
- Stevenson, D.E. and D. Blair. (1969). A Preliminary Report on the Inhalation Toxicity of High Concentrations of Dichlorvos. TLGR.0024.69. May, 1969.
- Ueda, K., and M. Nishimura. (1967). Effect of Vapona/Strips to Human Beings.
- Walker, A.I.T., D. Blair, D.E. Stevenson, and P.L. Chambers. (1972). An inhalation toxicity study with dichlorvos. *Arch Toxicol*. 30:1-7.

Studies that determine the effects of single/repeated exposures of dichlorvos via ingestion.

- Boyer A.C., L.J. Brown, M.B. Slomka, and C.H. Hine. (1977). Inhibition of human plasma cholinesterase by ingested dichlorvos: effect of formulation vehicle. *Toxicol. Appl. Pharm.* 41:389-394.
- Rider, J.A. (1967). Determination of the Minimal Incipient Toxicity of Dichlorvos in Humans. Shell Chemical Company, October, 1967.
- Slomka, M.B., and C. H. Hine. (1981). Clinical pharmacology of dichlorvos. *Acta Pharmacol. Et Toxicol* 49:105-108.

Additional information regarding the time course for achieving steady state after repeated exposure to dichlorvos.

- Boyer, A.C. (1975). Inhibition of Human Plasma Cholinesterase by Steady-State Concentration of Dichlovos. Technical Progress Report No. M-44-75. July, 1975.
- Coulston, F., and T. Griffin. (1977). Cholinesterase Activity and Neuromuscular Function of Rhesus Monkeys Exposed to DDVP Vapors. Document prepared by Institute of Comparative and Human Toxicology, Albany Medical College, Albany, NY and the International Center of Environmental Safety, Albany Medical College, Holloman AFB, NM.
- Hass, D.K., J.A. Collins, and J.K. Kodama. (1972). Effects of orally administered dichlorvos in Rhesus monkeys. *J.A.V.M.A.* 161(6):714-719.

Exposure Studies

Residential Pest-Strips:

Batth, Scrat S., J. Singh, and D.C. Villeneuve. (1973). Dichlorvos vaporizers: method for evaluation under simulated household use. J. Econ. Entom. 66(1):146-150.

Collins, R.D., and D.M. DeVries. (1970). Determination of Vapona Inserticide in Air and Food From Homes Treated with No-Pest Insecticide Strips. Shell Development Company. Technical Progress Report No. M-104-70, August, 1970.

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Page 3 4/06/99

- Collins, R.D., and D.M. DeVries. (1971). Determination of Vapona Insecticide in Air and Food From Homes Treated with No-Pest Insecticide Strips- II. Shell Development Company. Technical Progress Report No. M-60-71, September 28, 1971.
- Collins, R.D., and D.M. DeVries. (1972). Determination of Vapona Insecticide Residues in Air and Food From Homes Treated with Open/Close Insecticide Devices.

 Shell Development Company. Technical Progress Report No. M-2-72, August, 1970.
- Davies, L., and A.P. Woodbridge. (1979). The Performance of Modified Dichlorvos/PVC Slow-Release Matrices- A Review of the 1973 and 1974 Experimental Programme. Shell Biosciencese Laboratory BLTN.79.082. November 30.
- Elgar, K.E., B.L. Mathews, and P. Bosio. (1972). Dichlorvos residues in food arising from the domestic use of dichlorvos PVC strips. *Pestic Sci* 3:601-607.
- Elgar, K.E., B.L. Mathews, and P. Bosio (1972). Vapona strips in shops residues in foodstuffs. *Environ. Qual. Safety* 1:217-221.
- Elgar, K E., and B.D. Steer (1972). Dichlorvos concentrations in the air of houses arising from the use of dichlorvos PVC strips. *Pestic Sci.* 3:591-600.
- Elgar, K.E., and B.D. Steer. (1969). Vapona Generators- Air Concentration Studies Part :X- Vapona Generator Testing in France September December 1969. Shell Research Limited WKGR.0027.70, August 12, 1969.
- Leary, J.S., W.T. Keane, C. Fontenot, E.F. Feichmeir, D. Schultz, B.A. Koos, L. Hirsch, E.M. Lavor, C.C. Roan, and C.H. Hine. (1974). Safety evaluation in the home of polyvinyl chloride resin strip containing dichlorvos (DDVP). *Arch Environ. Health* 29:308-314.
- Leidy, R.B., and D.M. Stout II. (1996). Residues of chlorpyrifos and dichlorvos indoors following a perimeter house application. 211TH American Chemical Society National Meeting, New Orleans, LA. March 24-28. Abstracts of Papers American Chemical Society. 211 (1-2). AGRO 192.
- Lewis, R.G., A.E. Bond, D.E. Johnson, and J.P. Hsu. (1988). Measurements of atmospheric concentrations of common household pesticides a pilot study. *Environ Monit Assess.* 10 (1). 59-74.
- Shell Chemical Company. (1970). The Third Arizona Home Study: The Quantitation of DDVP Residues in Foods Consumed by Human Volunteers Exposed to No-Pest Strip Insecticide. May, 1970.
- Shell Research Limited. (1979). The Performance of Modified Dichlorvos/PVC Slow-Release Matrices A Review of the 1973 and 1974 Experimental Programmo.

- Steer, B.D. (1969) Vapona Generators -Air Concentration Studies Part IX- Vapona Strips Testing in UK, 1969. Shell Research Limited. WKGR.0159.69, July 31, 1969.
- Technical Service Laboratory. (1968). Vapona Generators- Air Concentration Studies. Part I- Vapona Strip (AC 6750)- Effect of Temperature and Humidity. WK.TR.0004/68 January 22, 1968.
- USEPA. 1990. Nonoccupational Pesticide Exposure Study (NOPES). Atmospheric Research and Exposure Assessment Laboratory. Research Triangle Park, NC. EPA/600/3-90/003. January. Also reported in: Whitmore, R.W., F.W. Immerman, D.E. Camann, A.E. Bond, R.G. Lewis, and J.L. Schaum. (1994). Nonoccupational exposures to pesticides for residents of two U.S. cities. *Arch. Env. Contam. Toxicol.* 26(1):47-59
- Zavon, M.R., and E. A. Kindel. (1966). Potential hazard in using dichlorvos insecticide resin. Organic Pesticides in the Environment. Advanced Chemical Series 60:177-186.

Occupational Pest-Strips:

Deer, H.M., E.D. Beck, and A.H. Roe. (1993). Respiratory exposure of museum personnel to dichlorvos insecticide. *Vet Hum Toxicol* 35(3):226-228.

Occupational Applicator:

- Das, Y.T., P.K. Taskar, H.D. Brown, and S.K. Chattopadhyay. (1983). Exposure of professional pest control operator to dichlorvos (DDVP) and residue on house structures. *Toxicol. Lett.* 17:95-99.
- Gold, R.E., and T. Holcslaw. (1985). Dermal and respiratory exposure of applicators and residents to dichlorvos-treated residences. In: *Dermal Exposure Related to Pesticide Use*, American Chemical Society, Washington, DC: 262-264.
- Gold, R.E., T. Holcslaw, D. Tupy, and J.B. Ballard. (1984). Dermal and respiratory exposure to applicators and occupants of residences treated with dichlorvos (DDVP). *Journal of Economic Entomology* 77(2):430-436.
- Hayes, A.L., R.A. Wise, and F.W. Weir. (1980). Assessment of occupational exposure to organophosphates in pest control operators. Am. Ind. Hyg. Assoc. J. 41(8):568-575.
- Menz, M., H. Luetkemeier, and K. Sachsse (1974). Long term exposure of factory, workers to dichlorvos (DDVP) insecticide. Arch Environ Health 28372-76.

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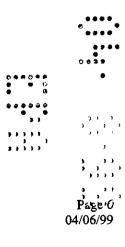
Page '5'

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- Wright, C.G., and R.B. Leidy. (1980). Insecticide residues in the air of buildings and pest control vehicles. *Bull. Environ. Contam. Toxicol.* Apr. 24(4):582-9.

Risk Assessment

Sensitive Sub-Populations and Inter-individual Variability:

- Cavagna, G., G. Locali, and E.C. Vigliana. (1970). Exposure of newborn babies to </Vapona>> insecticide. European Journal of Toxicology III:49-57.
- Cavagna, G., G. Locali, and E.C. Vigliana. (1969). Clinical effects of exposure to DDVP (Vapona) insecticide in hospital wards. *Arch Environ Health* 19:112-123.
- Cervoni, W.A., J. Oliver-Gonzalez, S. Kaye, and M.B. Slomka .(1969). Dichlorvos as a single dose intestinal anthelmintic therapy for man. A. J. Trop. Med. Hyg 18(4):912-919.
- Chavarria, A. Pena, J.C. Swartzwelder, V.M. Villarejos, E. Kotcher, and J. Arguedas. (1969). Dichlorvos, an effective broad spectrum anthelmintic. A. J. Trop. Med. Hyg. 18(6):907-911.
- Tracy, R.L., J.G. Woodcock, and S. Chodroff, S. (1960). Toxicological aspects of 2,2'-dichlorovinyl dimethylphosphate (DDVP) in cows, horses, and white rats. *J. Econ. Entomol.* 53(4):593-601.
- Uchiyama M., T. Kawakami, and H. Hiuga. (1967). Effect of Vapona Strips to human beings and the method of determination of DDVP concentration in the air. Pharmaceutical Dept., Faculty of Medicine, Tohoku University.
- Vigliani, E.C. (1971). Exposure of new born babies to Vapona insecticide. *Toxicol. Appl. Pharmacol.* 19:379-380.



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